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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,827	03/07/2007	Kenneth Feldmann	2750-1573PUS1	5253

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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

NOTIFICATION DATE	DELIVERY MODE
06/30/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/572,827	FELDMANN ET AL.	
	Examiner	Art Unit	
	STUART F. BAUM	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *10 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-16 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/21/06, 3/8/07, 3/28/08, 2/27/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *sequence search result (2)*.

DETAILED ACTION

1. Claims 1-20 are pending.

2. Applicant's election of Group I, claims 1-9, 1-16 and 18-20, including SEQ ID NO:35, 36 and 48 in the reply filed on 3/17/2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Claims 10 and 17 are withdrawn from consideration for being drawn to non-elected inventions.

3. Claims 1-9, 11-16 and 18-20, including SEQ ID NO:35, 36 and 48 are examined in the present office action.

Sequence Rules

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

Sequence identifiers are missing for example, from pages 63 and 64.

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules and a response to the issues set forth herein. Failure to fully comply with both of these requirements in the time period set forth in this Office action will be held to be non-responsive.

Claim Objection

5. Claims 1-4 and 16 are objected to for being drawn to non-elected inventions.

Written Description

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 4 and 13-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated nucleic acid molecule comprising a nucleotide sequence which encodes an amino acid sequence exhibiting 85% sequence identity, or a reverse sequence of said nucleotide sequence or a nucleic acid that hybridizes under the conditions listed in claim 1 wherein the sequence has the structure of SEQ ID NO:48 or a method comprising transforming a plant with said sequence or method of modulating flowering time or size of a plant, method of increasing the size of a plant or method of increasing the size or number of rosette leaves of a plant comprising transforming a plant with the nucleic acid of claim 1 or vector of claim 5.

Applicants disclose SEQ ID NO:35, 36 and 48 (sequence listing and page 19).

This rejection is made in part because SEQ ID NO:36 does not comprise SEQ ID NO:48 and SEQ ID NO:35 does not encode SEQ ID NO:48.

In additions, Applicants do not identify essential regions of proteins comprising SEQ ID NO:48, nor do Applicants describe any polynucleotide sequences that hybridize to any of the nucleotide molecules listed in claim 1 and encode a protein that when transformed into a plant increases the size of the plant or modulates flowering.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences encoding a protein falling within the scope of the claimed genus of polynucleotides which hybridize to any of the sequences of claim 1 and can be used in the recited methods. Applicants only disclose

SEQ ID NO:35, 36 and 48. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the protein of SEQ ID NO:48 or any of the sequences listed in claim 1, it remains unclear what features identify the proteins or the nucleic acid molecules. Both the prior art and the specification fail to disclose a correlation between the structure of the claimed sequences and the recited function. Since the genus of proteins has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Enablement

Claim Rejections - 35 USC § 112

7. Claims 1, 4-9, 11-16 and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior

art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to an isolated nucleic acid molecule comprising a nucleotide sequence which encodes an amino acid sequence exhibiting 85% sequence identity of SEQ ID NO:36, or a nucleic acid that hybridizes to the above sequence or a reverse sequence of said sequence under the conditions listed in claim 1 wherein the encoded protein has the structure of SEQ ID NO:48 or a reverse sequence of any of the sequences listed in claim 1(a)-1(b); vector, host cells, plant, plant cells, plant material or methods comprising said nucleic acid molecule.

Applicants disclose SEQ ID NO:35, 36 and 48 (sequence listing and page 19).

The Office contends that SEQ ID NO:36 does not comprise SEQ ID NO:48 and that SEQ ID NO:35 does not encode a polypeptide comprising SEQ ID NO:48. Results from a sequence search of SEQ ID NO:36 or SEQ ID NO:48 do not show that SEQ ID NO:36 comprises SEQ ID NO:48.

Applicants have not reduced to practice the claimed invention. Applicants have not transformed any plant with a nucleic acid encoding SEQ ID NO:48 nor have Applicants transformed a plant with a reverse sequence from claim 1. The Office contends that the reverse sequence would not encode any protein having the activity of SEQ ID NO:36, nor would the reverse sequence be useable to down-regulate SEQ ID NO:35 or any variant thereof. Applicants have not taught how one skilled in the art would use a reverse sequence or a plant comprising a reverse sequence.

Applicants have not provided examples or guidance for selecting a sequence out of the multitude of sequences that are encompassed by Applicant's broad claim language that gives the expected results when transformed into a plant. Transforming plants with heterologous genes that are involved in plant development produce unpredictable results. Kano-Murakami et al (1993, FEBS 334:365-368) teach introducing the *Oryza sativa* homeobox 1 (OSH1) gene into tobacco. OSH1 is a rice homologue of the *Knotted-1* homeobox gene from maize and would be encompassed by Applicant's broad claim language. Kano-Murakami et al teach transgenic tobacco plants comprising the OSH1 gene display a "range of phenotypes which include abnormalities in leaf and petal shape as well as stem height and number" (page 365, right column, 1st paragraph).

Applicants have not provided any teachings for one skilled in the art to predict and isolate nucleic acid sequences that encode a protein with the necessary activity to be operable in Applicants' invention. Applicants have not taught which regions of the respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences. Therefore, the instant specification fails to provide guidance for which amino acids of the protein of SEQ ID NO:48 can be altered, the type of alteration, and which amino acids must not be changed, to maintain activity of the encoded protein. The specification also fails to provide guidance for which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional protein.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences,

either by using non-disclosed fragments of SEQ ID NO:48 as probes or by designing primers to undisclosed regions of SEQ ID NO:48 and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed increase the size of a plant or the size or number of rosette leaves; or undue trial and error experimentation would be required for one of ordinary skill in the art to generate reverse sequence of any of the sequences encompassed in claim 1 and then to identify plants that exhibit any of the phenotypes recited in the method claims.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 5-9, 11-15 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Alexandrov et al (2000, EP 1033405 A2).

The claims are drawn to an isolated nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide exhibiting at least 85% sequence identity to SEQ ID NO:36, or a complement thereof, or a reverse sequence, or a nucleic acid capable of hybridizing to said nucleic acid molecule under the conditions listed in claim 1, or wherein the nucleic acid molecule is SEQ ID NO:35 or encodes the polypeptide of SEQ ID NO:36; a vector comprising said nucleic acid molecule, a host cell comprising said vector, a method of introducing an isolated nucleic acid into a host cell or method of transforming a host cell comprising contacting

said host cell with said vector, method of modulating flowering time or size of a plant, method of increasing the size of a plant or method of increasing the size or number of rosette leaves of a plant comprising transforming a plant with said nucleic acid or a plant, plant cell, plant material or seed comprising said nucleic acid.

Alexandrov et al disclose a nucleic acid sequence of SEQ ID NO:28673 that exhibits 100% identity to Applicants' SEQ ID NO:35 and encodes a protein having 100% sequence identity to Applicants' SEQ ID NO:36 (search results included). Alexandrov et al disclose a vector comprising said nucleic acid molecule, a host cell comprising said vector, a method of introducing an isolated nucleic acid into a host cell or method of transforming a host cell comprising contacting said host cell with said vector (see claims 1-34). Alexandrov et al also disclose a plant comprising said nucleic acid molecule which the Office interprets to read on Applicants' method claims because the limitations recited in the claims of Alexandrov et al are the same as those steps recited in Applicants' method claims, i.e., transforming a plant with said nucleic acid molecule. See *Integra LifeSciences I Ltd. V. Merck KGaA* 50 USPQ2d 1846, 1850 (DC SCalif 1999), which teaches that where the prior art teaches all of the required steps to practice the claimed method and no additional manipulation is required to produce the claimed result, then the prior art anticipates the claimed method and as such, Alexandrov et al anticipate the claimed invention.

9. Claims 1, 5-9, 11-15, 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Weigel (2001, Pub. No.: US 2001/0049831 A1).

The claims are drawn to an isolated nucleic acid molecule comprising a complement of a nucleotide sequence encoding a polypeptide exhibiting at least 85% sequence identity to SEQ ID NO:36,; a vector comprising said nucleic acid molecule, a host cell comprising said vector, a method of introducing an isolated nucleic acid into a host cell or method of transforming a host cell comprising contacting said host cell with said vector, method of modulating flowering time or size of a plant, method of increasing the size of a plant or method of increasing the size or number of rosette leaves of a plant comprising transforming a plant with said nucleic acid or a plant, plant cell, plant material or seed comprising said nucleic acid.

The Office interprets the recitation "a complement" to read on a single nucleotide.

Weigel discloses a nucleic acid sequence that comprises a complement of Applicants' nucleotide sequence as interpreted by the Office. Weigel discloses a vector, host cell plant and methods comprising said nucleic acid molecule (claims 1-58). See *Integra LifeSciences I Ltd. V. Merck KGaA* 50 USPQ2d 1846, 1850 (DC SCalif 1999), which teaches that where the prior art teaches all of the required steps to practice the claimed method and no additional manipulation is required to produce the claimed result, then the prior art anticipates the claimed method and as such, Weigel anticipates the claimed invention.

Amending claim 1(b) to recite --a nucleic acid which is the full complement..." will obviate the rejecttion.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 18-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to a seed of the transformed plant. Due to Mendelian inheritance of genes, a single gene introduced into a parent plant would only be transferred at most to half the male gametes and half the female gametes. This translates into only three quarters of the progeny having at least a single copy of the transgene and one quarter of the progeny would not carry a copy of the transgene. Given that there is no indication that there would be any other distinguishable characteristics of the claimed progeny (seeds), it is unclear whether the claimed seeds would be distinguishable from seeds that would occur in nature. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948), and *In re Bergy , Coats, and Malik* 195 USPQ 344, (CCPA) 1977. The amendment of the claims to recite that the seeds comprise the construct that was introduced into the parent would obviate the rejection.

11. Claims 8 and 9 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

The claim recites "A host cell comprising" which reads on a human being. Amending the claim to recite "An isolated host cell" will obviate the rejection.

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Stuart F. Baum/
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Art Unit 1638
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